

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 781037 R000

**Manufacturer:** Penumbra, Inc.

**Address:**

One Penumbra Place  
Alameda  
California  
94502  
USA

**Single Registration Number:** US-MF-000008514

**EU Authorised Representative:** Penumbra Europe GmbH

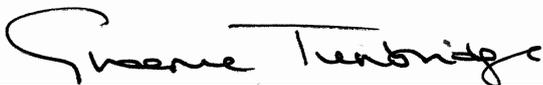
**Address:**

Am Borsigturm, 44  
13507 Berlin  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-27**

Current Issue Date: **2025-08-14**

Starting Validity Date: **2025-08-14**

Expiry Date: **2029-03-26**

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### Device Schedule:

**Intended Purpose as per the Instructions for Use:** The Penumbra Delivery Microcatheters are intended to assist in the delivery of diagnostic agents and therapeutic devices to the vasculature.

**Risk Classification:** Class III

**Type (Codes as per (EU) 2017/2185):** MDN 1203

**Basic UDI-DI:** 081454801PDMET

Model	Device Name
PXSLIMSTR	PX SLIM 150 cm, Straight tip
PXSLIM045	PX SLIM 150 cm, 45° tip
PXSLIM090	PX SLIM 150 cm, 90° tip
PXSLIM130	PX SLIM 150 cm, 130° tip
PXSLIM160STR	PX SLIM 160 cm, Straight tip
PXSLIM160045	PX SLIM 160 cm, 45° tip
PXSLIM160090	PX SLIM 160 cm, 90° tip
PXSLIM160130	PX SLIM 160 cm, 130° tip
VEL150STR	Velocity 150 cm, Straight tip
VEL150045	Velocity 150 cm, 45° tip
VEL150090	Velocity 150 cm, 90° tip
VEL150130	Velocity 150 cm, 130° tip
VEL160STR	Velocity 160 cm, Straight tip
VEL160045	Velocity 160 cm, 45° tip
VEL160090	Velocity 160 cm, 90° tip
VEL160130	Velocity 160 cm, 130° tip
PXSLIMLAN115STR	LANTERN 115 cm, Straight tip
PXSLIMLAN115T45	LANTERN 115 cm, 45° tip
PXSLIMLAN115T90	LANTERN 115 cm, 90° tip
PXSLIMLAN115T130	LANTERN 115 cm, 130° tip

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Model	Device Name
PXSLIMLAN135STR	LANTERN 135 cm, Straight tip
PXSLIMLAN135T45	LANTERN 135 cm, 45° tip
PXSLIMLAN135T90	LANTERN 135 cm, 90° tip
PXSLIMLAN135T130	LANTERN 135 cm, 130° tip
PXSLIMLAN150STR	LANTERN 150 cm, Straight tip
PXSLIMLAN150T45	LANTERN 150 cm, 45° tip
PXSLIMLAN150T90	LANTERN 150 cm, 90° tip
PXSLIMLAN150T130	LANTERN 150 cm, 130° tip
PXSLIMLAN160STR	LANTERN 160 cm, Straight tip
PXSLIMLAN160T45	LANTERN 160 cm, 45° tip
PXSLIMLAN160T90	LANTERN 160 cm, 90° tip
PXSLIMLAN160T130	LANTERN 160 cm, 130° tip
PXACSTR	ACCESS25, 150cm, Straight Tip
PXAC045	ACCESS25, 150cm, 45° Tip
PXAC090	ACCESS25, 150cm, 90° Tip
PXAC130	ACCESS25, 150cm, 130° Tip
PXAC160STR	ACCESS25, 160cm, Straight Tip
PXAC160T45	ACCESS25, 160cm, 45° Tip
PXAC160T90	ACCESS25, 160cm, 90° Tip
PXAC160T130	ACCESS25, 160cm, 130° Tip

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Model	Device Name
PXAC170STR	ACCESS25, 170cm, Straight Tip
PXAC170T45	ACCESS25, 170cm, 45° Tip
PXAC170T90	ACCESS25, 170cm, 90° Tip
PXAC170T130	ACCESS25, 170cm, 130° Tip
VEL25STR150	ACCESS25, 150cm, Straight Tip
VEL25T045150	ACCESS25, 150cm, 45° Tip
VEL25T090150	ACCESS25, 150cm, 90° Tip
VEL25T130150	ACCESS25, 150cm, 130° Tip
VEL25STR	ACCESS25, 160cm, Straight Tip
VEL25045	ACCESS25, 160cm, 45° Tip
VEL25090	ACCESS25, 160cm, 90° Tip
VEL25130	ACCESS25, 160cm, 130° Tip
VEL25STR170	ACCESS25, 170cm, Straight Tip
VEL25T045170	ACCESS25, 170cm, 45° Tip
VEL25T090170	ACCESS25, 170cm, 90° Tip
VEL25T130170	ACCESS25, 170cm, 130° Tip

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
2024-03-27	3792144	Issued
Current	30319581	Supplemented– Addition of ACCESS25 Delivery Microcatheter to device table.



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.